DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael D. Moss
Chief Executive Officer
Moss Tubes, Inc.
749 Columbia Turnpike
East Greenbush, New York 12061

November 16, 2000

Ref: NYK-2001-20

Dear Mr. Moss:

During an inspection of your firm located at the above address, on October 2 through 13, 2000, our investigator determined that your firm is responsible for the manufacture of Moss Nasal Tubes, Mark IV. Nasal tubes are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to perform a complete and documented investigation as required by 21 CFR 820.90(a) regarding the sterility test failure after the one half sterilization cycle validation study of Moss Nasal Tubes, Mark IV, lot 72700. The lot was shipped, in part, without documented justification for use of nonconforming product as required by 21 CFR 820.90(b)(1).

2. Failure to establish and maintain adequate procedures for design changes as required by 21 CFR 820.30(i).

We acknowledge receipt of your letter of November 2, 2000 responding to the Inspectional Observations issued on the form FDA 483 at the end of the inspection. Your response to observations 1 & 2 consists of an investigation of the sterility test failure with plans to conduct additional sterility testing of lot 72700. Please provide us with copies of any retesting results. The investigation into the failing test result should have been completed and documented prior to shipment of the device. Your response fails to address what procedures and controls will

be implemented so that investigations are complete and documented to ensure proper evaluation of nonconforming products. A similar observation was brought to your attention at the end of the previous inspection of your firm conducted on March 30 through April 8, 1999. That form FDA 483 included the observation that complaints of failures associated with gastrostomy tubes were not investigated. Please provide a more global response regarding the handling and control of non-conformities, failures, and out of specification test results. Also, more specifically, your response states that the laboratory investigation regarding lot 72700 concluded that the test failure was due to the possibility of mishandling the test sample. However, during the inspection our investigator collected documents relating to the laboratory testing of the subject test. The laboratory's notation on the fax coversheet to you states that their investigation did not result in a direct laboratory cause. Please explain your conclusion in view of this differing information.

Your response letter addresses FDA 483 observation # 4 by stating the design change control procedures will be implemented by January 1, 2001. This observation was also previously brought to your attention on the form FDA 483 issued on April 8, 1999, yet remains uncorrected. The design change control procedure should be established promptly.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and/or quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433 (Tel. 718/340-7000 ext. 5585).

Sincerely,

Edward W. Thomas
Acting District Director